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March 12, 2021

VIA EMAIL
Hon. Michael A. Shipp, U.S.D.J.
U.S. District Court
District of New Jersey
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: ***Amgen Inc. v. Sandoz Inc.,***
Civ. Action No. 18-11026-MAS-DEA (con.) (D.N.J.)

Dear Judge Shipp:

This firm, together with Covington & Burling LLP and Sidley Austin LLP, represents Plaintiff Amgen Inc. ("Amgen") in the above-captioned consolidated Hatch-Waxman litigation. Pursuant to the Court's Pretrial Order dated February 11, 2021 (ECF No. 323) ("Pretrial Order"), we submit this letter jointly on behalf of all parties in this consolidated action regarding i) consolidation for purposes of trial, ii) a request for additional trial days, and iii) to provide the Court with the parties' tentative lists of anticipated witnesses at trial.

I. Consolidation

The parties believe that the cases currently consolidated for discovery purposes[1] should continue to be consolidated for trial. As the issues and witnesses overlap substantially between Defendants, the parties believe consolidation would be the most efficient use of the Court's and the parties' time and resources. Depending on the issues remaining for trial, the parties may later propose that the courtroom be sealed during the presentation of certain documentary evidence or witness testimony.

II. Request for Additional Trial Days

A. Plaintiff's Position

[1] Civil Action Nos. 18-11026; 18-11156; 18-11213; 18-11216; 18-11219; 18-11262; 18-11265; 18-11267; 18-11269; 18-11545; and 19-18806.

As the case stands today, Plaintiff anticipates that it will need an additional **two and a half** trial days. This estimate assumes that the ten days of trial time currently allotted by the Court will be split equally between Plaintiff and Defendants, and that each trial day is 6.5 hours,[2] taking morning, lunch and afternoon breaks into account. Plaintiff proposes that additional trial days be scheduled during the week of June 7-11, 2021.

There are ten Defendants remaining in the consolidated action.[3] Infringement continues to be at issue for at least one patent for eight Defendants. Three Defendants—Aurobindo, Cipla, and MSN—have not articulated any defense on the issue of infringement for any patent asserted against them, and their assertions, below, that they expect to resolve this issue before trial do not alleviate Plaintiff's responsibility to plan for the case as it exists now.[4] Another Defendant—Pharmascience—has not articulated a defense on the issue of infringement for five of the six patents asserted against it.[5] Yet so far all of these Defendants have refused Plaintiff's reasonable requests to stipulate to infringement over the past five months. Such stipulations would streamline the issues for trial and conserve the parties' and Court's time and effort otherwise spent on unrebutted infringement cases. Plaintiff estimates that it will take one full trial day to introduce evidence on its unrebutted infringement proofs and if Defendants force it to do so, Plaintiff proposes that such time should be charged to Defendants.

Plaintiff has been, and plans to continue, working with Defendants to reduce the number of issues for trial, including seeking infringement stipulations where a Defendant has not advanced a substantive non-infringement defense, reducing the number of asserted patent claims and reducing the scope of Defendants' invalidity defenses. Amgen disputes Defendants' assertions that it has "refused" their proposal to further narrow the case: Amgen has already

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[2] Amgen would appreciate the Court's guidance as to how many hours of trial the parties should anticipate per day.

[3] Alkem Laboratories Ltd. ("Alkem"); Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc. (collectively, "Aurobindo"); Cipla Ltd. ("Cipla"); Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"); MSN Laboratories Private Ltd. ("MSN"); Pharmascience Inc. ("Pharmascience"); Prinston Pharmaceutical Inc. ("Prinston"); Sandoz Inc. ("Sandoz"); Torrent Pharmaceuticals Ltd. ("Torrent"); and Zydus Pharmaceuticals (USA) Inc. ("Zydus").

[4] With respect to MSN, Amgen provided counteredits to MSN's proposal on February 12, to which MSN informed Amgen that it "does not agree with Amgen's revisions," with no further explanation. To date, MSN has refused to engage with Amgen to discuss a path forward, despite several emails requesting more information and to meet and confer.

[5] With respect to Pharmascience, if Pharmascience believes that a specific claim in the stipulation should not be included, it should tell Amgen which claim and send Amgen a redline, which it has thus far has not done. Moreover, whether Pharmascience infringes a claim has no relation to the number of claims asserted.

reduced the number of asserted claims in this case by nearly 70%. Moreover, in November 2020, Amgen suggested that the parties agree by no later than March 26, 2021 to a proposal to further narrow the case. Defendants never responded to this suggestion, or offered a counter suggestion, although they have represented to the Court that they "remain committed to further reducing defenses and references by a date certain following completion of expert reports." *See* Jan. 5, 2021 Ltr. to J. Apert from T. McCormick, at 5.

Should Aurobindo, Cipla, Pharmascience and MSN stipulate to infringement, Plaintiff anticipates that it will need only an additional **one and a half** trial days to address the issues that remain in this case. Of course, Plaintiff will promptly inform the Court if any agreements are reached between Plaintiff and Defendants (including settlement) that would result in a reduction of the days needed for trial.

As detailed further below, the parties estimate that witness testimony alone will require 75.55 hours, including 47.4 hours for Plaintiff's witnesses and 28.15 hours for Defendants' witnesses.[6] In addition to witness testimony, Plaintiff's trial time estimates takes into account time for opening statements, deposition designations, and objections. Plaintiff's estimates also assume that time spent on objections will be charged to the objecting party if the objection is not sustained. Specifically, if a party makes an objection during trial and the objection is overruled, the aggregate time consumed in addressing that objection will be charged to the party making the objection. Conversely, if a party makes an objection that is sustained, the time spent making that objection will be charged to the other side. Plaintiff is otherwise unable to provide an accurate estimate of the trial time needed because Plaintiff does not have any way to control the amount of time Defendants may spend objecting during Plaintiff's presentation of evidence. Plaintiff also believes that its proposed approach will limit objections by both parties during trial to only those that an objecting party thinks are truly meritorious.

B. Defendants' Position

Defendants believe that 10 trial days should be sufficient for both sides to fully and efficiently present their cases, assuming that each day will allow for 7 hours of trial time. Defendants have provided estimates of the tentative length of testimony for each witness in order to fit within the 10 trial days allocated by the Court, and believe that if the parties work efficiently, this case can be tried without additional days. That said, should the Court inform the parties that trial days will allow less than 7 hours of trial time per day, Defendants may request one or more additional trial days. One way to ensure that the case is tried within the 10 trial days that the Court has provided is for Plaintiff to narrow the number of asserted patents and claims. As noted below in the discussion of infringement stipulations below, so far Plaintiffs have

[6] This estimate accounts for all claims and defenses currently at issue, including time needed for witnesses to address infringement for those Defendants who have not advanced a substantive non-infringement defense yet continue to refuse to stipulate to infringement.

refused Defendants' proposal to narrow the number of asserted patents and claims (which would likewise narrow the infringement and invalidity disputes). A narrowing of the asserted patents and claims seems appropriate considering that, even with infringement stipulations, Plaintiff requests an additional 1.5 trial days (which, assuming this additional time is equitably provided to each side, is an additional 3 trial days). In addition to narrowing infringement issues, a reduction in the number of asserted patents and claims would also narrow invalidity issues.

Whatever the length of trial time permitted, it should be split evenly between the two sides. Should the Court agree to provide Plaintiff with the additional 1.5-2.5 days of trial that it requests, Defendants request that they be provided an equal amount of additional time. There is no reason why Defendants should be given less time to present their case than Plaintiff, particularly here where multiple Defendants are being required to coordinate their cases. Defendants agree to share trial time amongst themselves but believe that, collectively, they should have the same amount of trial time as Plaintiff.

Plaintiff claims that one of the additional trial days that it has requested is necessary only because Aurobindo, Cipla, Pharmascience and MSN have, in Plaintiff's words, "refused Plaintiff's reasonable requests to stipulate to infringement over the past five months." Defendants dispute this characterization of events. With respect to Aurobindo, Aurobindo has informed Amgen that it is considering Amgen's proposal, and Aurobindo is confident that the parties will reach agreement regarding the infringement stipulation prior to trial. With respect to Cipla, Cipla and Amgen continue to negotiate the terms of a stipulation, and Cipla expects the parties to reach agreement in advance of trial. With respect to Pharmascience, Pharmascience has specifically raised concerns that Plaintiff's proposed stipulation includes claims that are not now, nor have they ever, been asserted against Pharmascience. Pharmascience has also proposed that Plaintiff narrow the set of asserted claims to a more reasonable stipulation. Thus far, Plaintiff has refused Pharmascience's concerns and proposal. With respect to MSN, on February 10, 2021 MSN's counsel proposed a Stipulation of Infringement for every patent claim for which a stipulation was requested by Amgen, but Amgen said that the proposed stipulation was not acceptable.

In addition to 33 hours of witness testimony, Defendants' trial time estimates take into account time for opening statements, deposition designations, and objections, all of which Defendants believe should be counted against the overall trial time limits for each side. Defendants agree with Plaintiff that time spent on denied objections will be charged to the objecting party and on sustained objections will be charged to the other party.

III. Tentative List of Anticipated Witnesses

The following tables set forth Plaintiff's and Defendants' tentative list of witnesses, and tentative length of testimony for each witness, as anticipated at this time based on the claims and defenses currently at issue in the consolidated action.

Plaintiff's Witnesses

	Witness Name	State or Country of Residence	Anticipated Length of Testimony – PLAINTIFF	Anticipated Length of Testimony – DEFS.	Anticipated Length of Testimony – TOTAL
1	Dr. Andrew Alexis	New York	7.5 hours	4.5 hours	12 hours
2	Dr. Martyn Davies	United Kingdom*	0.75 hours	0.33 hours	1.08 hours
3	Dr. Stephen Davies	United Kingdom*	5.75 hours	2.75 hours	8.5 hours
4	Dr. Robert Day	Pennsylvania	1 hour	0.5 hours	1.5 hours
5	Dr. Fabia Gozzo	Switzerland*	0.75 hours	0.33 hours	1.08 hours
6	Dr. Susan Kim	New Jersey	0.75 hours	0.33 hours	1.08 hours
7	Dr. Richard Knowles	United Kingdom*	3 hours	1 hour	4 hours
8	Dr. Hon-Wah Man	New Jersey	1.25 hours	0.5 hours	1.75 hours
9	Dr. Philip Mease	Washington	2.75 hours	1 hour	3.75 hours
10	Christopher Mercer	United Kingdom*	0.75 hours	0.33 hours	1.08 hours
11	Dr. Allan Myerson	Massachusetts	3.5 hours	1.33 hours	4.83 hours
12	Dr. Peter Schafer	New Jersey	1 hour	0.5 hours	1.5 hours
13	William Smith	Arizona	1.5 hours	0.75 hours	2.25 hours
14	Dr. Ronald Thisted	Illinois	1 hour	0.5 hours	1.5 hours
15	Dr. Christopher Vellturo	Massachusetts	1 hour	0.5 hours	1.5 hours

	Witness Name	State or Country of Residence	Anticipated Length of Testimony – PLAINTIFF	Anticipated Length of Testimony – DEFS.	Anticipated Length of Testimony – TOTAL
TOTAL			32.25 hours	15.15 hours	47.4 hours

*For an in-person trial, Plaintiff expects that at least its witnesses located outside of the United States will be unable to travel to the United States for trial in light of the current global situation and will therefore need to participate remotely.

In addition, Plaintiff estimates that it will need a total of 3 hours for all witnesses to be called by designation. Plaintiff's tentative list of anticipated witnesses to be called by designation is as follows: Nidhi Bagree, Dr. Kondal Reddy Bairy, Shobha Chagam, Renata Degady, Brian Des Islet, Chintan Dholakia, Dr. Santosh Diwakar, Dr. Sanjay Karale, Goviendarajan Kesavan, Kent Major, Dr. George Muller, Vishnubhotla Nagaprasad, Ravikumar Puppala, Elizabeth Purcell, Dr. Sujay Rajhans, Dr. Patricia Rohane, Anand Saxena, Christine Walton, Dr. Lijie Wang, and Dr. Jean Xu.[7]

Defendants' Witnesses

	Witness Name	State or Country of Residence	Anticipated Length of Testimony – DEFS	Anticipated Length of Testimony – PLAINTIFF	Anticipated Length of Testimony – TOTAL
16	Dr. Elaine Gilmore	New York	2 hours	1.25 hours	3.25 hours
17	Dr. Gordon Gribble	New Hampshire	2 hours	1.5 hours	3.5 hours
18	Dr. Simon Helfgott	Massachusetts	1.5 hours	0.75 hours	2.25 hours
19	Dr. Clive Page	United Kingdom	2 hours	1.5 hours	3.5 hours
20	Dr. Mark Sacchetti	Wisconsin	1.5 hours	1 hour	2.5 hours

[7] Amgen objects to Defendants calling Chintan Dholakia, Santosh Diwakar, and Goviendarajan Kesavan by deposition designation as they are witnesses under the control of Zydus.

	Witness Name	State or Country of Residence	Anticipated Length of Testimony – DEFS	Anticipated Length of Testimony – PLAINTIFF	Anticipated Length of Testimony – TOTAL
21	Dr. Jonathan Steed	United Kingdom	1.5 hours	1.25 hours	2.75 hours
22	Prof. Daniel Scharfstein	Utah	1 hour	0.5 hours	1.5 hours
23	Ivan Hofmann	Pennsylvania	1 hour	0.5 hours	1.5 hours
24	Dr. Charles Douchy	Georgia	1.5 hours	0.75 hours	2.25 hours
25	Dr. Samuel Hwang	California	1.5 hours	0.5 hours	2 hours
26	Dr. Steven Miller	Pennsylvania	1.5 hours	0.75 hours	2.25 hours
27	Sanjay Gupta (Chief Executive Officer, Torrent Pharma, Inc. USA)	New Jersey	0.25 hours	0.2 hours	0.45 hours
28	Ujwal Chhabra (Associate Vice President of Regulatory Affairs Department, Alkem Laboratories Ltd.)	India	0.25 hours	0.2 hours	0.45 hours
TOTAL			17.5 hours	10.65 hours	28.15 hours

Of these witnesses, Dr. Helfgott's hospital system employer currently has rules against business travel out of state, and it is unclear whether these rules will be relaxed by June. Drs. Page and Steed both reside in the United Kingdom, and it is not yet known what the rules for travel from the United Kingdom to the United States will be in June. With respect to Dr. Douchy, he is a dermatologist with a busy practice in the State of Georgia and it will likely be difficult for Dr. Douchy and his patients for Dr. Douchy to be available in New Jersey on short notice. Dr.

Douchy will only testify with respect to Prinston's non-infringement of one patent. Finally, Ujwal Chhabra will likely not be able to travel to the United States from India based on current travel restrictions. With respect to all other witnesses, there are no currently anticipated issues that would prevent their travel to trial in June of this year.

Defendants estimate that they will need a total of 2.25 hours for all witnesses to be called by designation. Defendants' tentative list of anticipated witnesses to be called by designation is as follows: George Muller, Richard Person, Patricia Rohane, Jean Xu, Chintan Dholakia, Santosh Diwakar, and Goviendarajan Kesavan.

* * *

We appreciate Your Honor's kind attention to this matter. The parties can be available at the Court's convenience to discuss these issues, if it would be helpful.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier

cc: All counsel of record (via ECF and email)